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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/757,683      | 01/13/2004  | Daniel Perreault     | 1001.1723101        | 4121             |

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EXAMINER

SMITH, PAUL B

ART UNIT PAPER NUMBER

3763

DATE MAILED: 09/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/757,683             | PERREAULT ET AL.    |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Paul B. Smith          | 3763                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 1/13/2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 January 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>5/14/04 5/2/05</u>  | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Information Disclosure Statement***

1. The information disclosure statement (IDS) submitted on 5/14/2004 and 5/02/2005 are acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner considers the references cited therein.

### ***Drawings***

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the inner lubricious layer, tie layer and outer layer as disclosed in claims 12 and 13 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.
3. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement-drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering

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of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the examiner does not accept the changes, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as his invention.

5. Claim 14 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 14 recites the limitation "reinforcing tube" in line 1. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1- 4, 6-11, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Sagae ('637).

9. Sagae discloses a catheter comprising an inflatable balloon (3), a catheter shaft (2), an inflation lumen (6), a guidewire lumen (4), a guidewire receiving tube (9), a tubular member (1), an outer member (2) and a reinforcing sleeve (14). (See Figure 1) The reinforcing sleeve is attached to the outer member at a tack point. (See Column 5 Line 60-68) The reinforcing sleeve extends proximally to and past the tack point.

10. Thus, it appears that Sagae reasonably teaches every element of claims 1-4, 6-11 and 14.

11. Claims 15-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Sugiyama *et al.* ('895).

12. Sugiyama *et al.* discloses a catheter comprising a first elongate member (3), a second elongate member (1), a third elongate member (2), and an inflatable balloon member (10). (See Figure 2) The third elongate member comprises an elastic material such as ethylene-propylene. (See Column 6 Lines 36-44) The third elongate member is connected to the first elongate member by an adhesive material or by thermal fusion. (See Column 2 Lines 58-66)

13. Thus, it appears that Sugiyama *et al.* reasonably teaches every element of claims 15-22.

***Claim Rejections - 35 USC § 103***

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

16. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sagae ('637).

17. Sagae discloses a catheter comprising an inflatable balloon (3), a catheter shaft (2), an inflation lumen (6), a guidewire lumen (4), a guidewire receiving tube (9), a tubular member (1), an outer member (2) and a reinforcing sleeve (14). (See Figure 1)

The reinforcing sleeve is attached to the outer member at a tack point. (See Column 5 Line 60-68) The reinforcing sleeve extends proximally to and past the tack point.

18. Sagae fails to disclose a reinforcing sleeve that extends at least 15 cm proximally past the tack point.

19. It would have been obvious to one of ordinary skill in the art to modify as claimed as a mere design choice lacking any criticality of length as being merely preferable for strengthening the area depending on the length of area in need of reinforcing where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art

20. Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sagae ('637) in view of Kastenhofer ('977).

21. Sagae discloses a catheter comprising an inflatable balloon (3), a catheter shaft (2), an inflation lumen (6), a guidewire lumen (4), a guidewire receiving tube (9), a tubular member (1), an outer member (2) and a reinforcing sleeve (14). (See Figure 1) The reinforcing sleeve is attached to the outer member at a tack point. (See Column 5 Line 60-68) The reinforcing sleeve extends proximally to and past the tack point.

22. Sagae fails to disclose a guidewire tube comprising an inner lubricious layer, a tie layer and an outer layer.

23. Kastenhofer teaches a balloon catheter with a guidewire tube comprising an inner layer (2), outer layer (3) and a mediator layer (4). (See Figure 1) Where the inner layer is taught to have a very low friction coefficient and the outer layer is taught to have a non-kinking capacity. (See Column 5 Line 7-10)

24. Thus, it would have been obvious to one of ordinary skill in the art to modify the disclosure of Sagae with the teachings of Kastenhofer to provide a multilayer guidewire tube.

### ***Conclusion***

25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul B. Smith whose telephone number is 571-272-6022. The examiner can normally be reached on 8 am - 4 pm.

26. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.




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27. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Paul B Smith  
Examiner  
Art Unit 3763

PBS  
August 29, 2006



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